

REMARKS

With this response, claims 49, 52-56, 58, 61-62, 65, 68-72, 74, 77-78, 81, 84-88, 90-94, and 97-111 are pending. Claims 49, 52-55, 58, 61 and 97-101 have been amended without prejudice or disclaimer. Claims 103-111 are newly added. Support for the foregoing amendment can be found throughout the specification and the claims as originally filed; see, for example, in the Specification at page 8, lines 13 - 21; Example 3 and Table 1.

At the outset, Applicant thanks the Examiner for indicating that a soybean plant transformed with the soy fad2-1A intron of SEQ ID NO:2 having a fatty acid composition of about 26-80% oleic acid, about 2.97-49.92% linoleic acid, and about 3.38-8.81% linolenic acid is free of the prior art. Office Action at page 4. Applicant also thanks the Examiner for indicating that the specification is enabling for a soybean plant having a nucleic acid molecule comprising a promoter functional in a plant host cell operably linked to a polynucleotide having the sequence SEQ ID NO:2 or a complement thereof, wherein a seed of said soybean plant has a fatty acid composition of about 26-80% oleic acid, about 2.97-49.92% linoleic acid, and about 3.38-8.81% linolenic acid. Office Action at page 2.

I. Rejection under 35 U.S.C. § 112, First Paragraph, Scope of Enablement

In rejecting claims 49-50, 52-58, 61-62, and 97-102¹ under 35 U.S.C. §112, first paragraph, the Examiner alleges that the specification “does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.” Office Action at page 3. The Examiner goes on to assert that the specification, while being enabling for a soybean plant having a nucleic acid molecule comprising a promoter functional in a plant host cell operably linked to a polynucleotide having the sequence SEQ ID NO: 2 or a compliment thereof, wherein a seed of said soybean plant has a fatty acid composition of about 26-80% oleic acid, about 2.97-49.92% linoleic acid, and about 3.38-8.81% linolenic acid, does not reasonably provide enablement for a

¹ Claims 50, 52-57 are dependent on claim 49; Claims 61-62 are dependent on claim 58; and Claims 98-102 are dependent on claim 97.

soybean plant having a nucleic acid molecule comprising a promoter functional in a plant host cell operably linked to a polynucleotide having a sequence at least 70% identical to SEQ ID NO:2 or a complement thereof, wherein a seed of said soybean plant has a fatty acid composition of about 26-80% oleic acid, about 2.97-49.92% linoleic acid. *Id.* Applicant respectfully disagrees.

Applicant respectfully disagrees with the Examiner's scope of enablement rejections under 35 U.S.C. §112, first paragraph. However, in order to facilitate prosecution, Applicant has amended claims 49, 52-55, 58, 61 and 97-101 without prejudice or disclaimer.

Applicant thanks the Examiner for the acknowledgement that the specification "provides examples of sense and antisense constructs of SEQ ID NO: 2 transformed into soybean plants to produce soybean plants having seeds with the claimed ranges of fatty acid composition." Office Action at page 3. Indeed, the specification provides evidence that the claimed sequences can be used to modify the fatty acid composition in a plant; see, for example, Specification at page 6, lines 16-24; page 25, line 4 - page 27, line 11; Example 3 and Table 1. Given this, Applicant respectfully submits that one of ordinary skill in the art would have the ability to practice the claimed invention without undue experimentation.

Applicant further submits that a soybean plant having a nucleic acid molecule comprising a promoter functional in a plant host cell operably linked to a polynucleotide that has at least 95%, 97%, 98%, or 99% identity to SEQ ID NO: 2, a complement thereof, or a fragment of either, wherein a seed of said soybean plant has a fatty acid composition of about 26-80% oleic acid, about 2.97-49.92% linoleic acid, and about 3.38-8.81% linolenic acid, satisfies 35 U.S.C. §112, first paragraph. For example, given at least Table 1 and Example 3, one of ordinary skill in the art having read the specification would have the ability to make nucleotide substitutions, without undue experimentation, and still maintain a fatty acid profile within the claimed invention. To the extent that any additional experimentation may be required, Applicant notes that the performance of routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404; *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

Applicant respectfully disagrees with the Examiner's assertion that De Luca *et al.* (*AgBiotech News and Information* Vol. 5 No. 6 :255N-229N, 2002) is applicable to the claimed invention and shows the "general unpredictability of using a sequence to transform a plant and modify the lipid composition of a plant." Office Action at page 3. At the outset, Applicant respectfully submits that "general applicability" is not enough. To the extent that the Office suggests there is a requirement for *a priori* predictability without recourse to any experimentation, that position is without legal support. *Cf. Atlas Powder Co. v. E. I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984) ("[t]hat some experimentation is necessary does not preclude enablement"). The proper test of enablement in such a situation is whether the disclosure "adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility." *See In re Vaeck*, 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991).

Applicant has provided considerable direction and guidance, and have presented working examples such that it is within the level of ordinary skill in the art to practice the invention without undue experimentation. In contrast, the Examiner has not provided specific or sufficient evidence to cast doubt on the guidance provided in the specification. Rather, the Examiner has provided generalizations regarding a lack of predictability in the art and the need for some experimentation.

Accordingly, for at least these reasons, it is submitted that the claims are sufficiently enabled under 35 U.S.C. § 112, first paragraph, and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding objection and rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5186 should any additional information be necessary for allowance.

Respectfully submitted,



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